DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2014

NovaBone Products, LLC
Ms. Lisa Simpson
Manager, Regulatory Affairs
13510 NW US Highway 441
Alachua, Florida 32615

Re: K141207
Trade/Device Name: Novabone BIOACTIVE Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: October 2, 2014
Received: October 3, 2014

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director, Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K141207

Device Name

NovaBone BIOACTIVE Strip

Indications for Use *(Describe)*

NovaBone Bioactive Strip bone graft devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Bioactive Strip is indicated to be gently placed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NovaBone Bioactive Strip must be hydrated with autogenous bone marrow aspirate prior to implantation. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
BIOACTIVE Strip

DRIVING INNOVATION IN OSTEOBIOLOGICS

Date Prepared: October 27, 2014

510(k) Holder / Submitter:

Name: NovaBone Products, LLC
Address: 13510 NW US Highway 441
Alachua, FL 32615

Telephone: (386) 462-7661, ext 216
Fax: (386) 462-7525

Contact: Lisa Simpson / Manager, Regulatory Affairs

Name of Device:

Trade Names: NovaBone BIOACTIVE Strip
Common Name: Osteoconductive Bone Void Filler
Synthetic Resorbable Bone Graft Material

Regulation Number: 21 CFR 888.3045

Regulation Name: Bone Void Filler

Regulatory Class: Class II

Product Code: MQV

Legally Marketed Predicate Devices:

K090731 / K060432	NovaBone Porous – Synthetic Bone Graft Scaffold (primary predicate)
K083033	Orthovita Vitoss Foam Bone Graft Substitute

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BIOACTIVE Strip

Device Description

NovaBone BIOACTIVE Strip is an osteoconductive bioactive device used for grafting osseous defects. The device is a mixture of bioactive calcium-phospho-silicate granules and a collagen binder. The bioactive glass particulate is composed solely of elements that exist in normal bone (Ca, P, Na, Si, O). The binder consists of bovine collagen. When hydrated with bone marrow aspirate, the device absorbs fluids to form a flexible graft matrix that is applied directly to the intended graft site. During healing, the graft particulate is absorbed and remodeled into new bone.

BIOACTIVE Strips are flexible after hydration and are not intended to be load-bearing. Therefore, bulk physical /mechanical properties such as compressive and tensile strengths are not applicable to device properties. The device is sterilized to a sterility assurance level of 10^{-6} using ethylene oxide.

Intended Use / Indications for Use

NovaBone Bioactive Strip bone graft devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Bioactive Strip is indicated to be gently placed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NovaBone Bioactive Strip must be hydrated with autogenous bone marrow aspirate prior to implantation. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Technological Characteristics and Substantial Equivalence

NovaBone BIOACTIVE Strip and the predicate devices utilize biocompatible materials that fill bony voids and provide an environment for bone regeneration. The host bone remodels through an osteoconductive process as new bone grows into the matrix of the graft materials. The graft materials are slowly resorbed and replaced by the host bone. The proposed and predicate devices are not intended to be load bearing and are only intended to be used in defects that are not intrinsic to the stability of the bony structure. BIOACTIVE Strip and the predicates have similar mode of action, therefore no new issues of safety or effectiveness are presented.

BIOACTIVE Strip and the primary predicate (NovaBone Porous, K090731) incorporate the same bioactive component, a three-dimensional porous structure comprised of Bioglass® 45S5, an inorganic calcium phospho-silicate, which

510(k) SUMMARY
BIOACTIVE Strip

conforms to ASTM F1538-03. Therefore, no new issues of safety or effectiveness are raised by the bioactive agent in the proposed BIOACTIVE Strip device.

Similar to the reference predicate (Vitoss), BIOACTIVE Strip includes a handling agent derived from bovine collagen; however, the primary predicate, NovaBone Porous (K090731) is 100% bioactive glass (without a handling agent). A panel of biocompatibility tests demonstrates that BIOACTIVE Strip materials do not raise new issues of biocompatibility safety.

Functional *in vivo* testing in an animal model (rabbit femoral defect) was performed on BIOACTIVE Strip using the primary predicate (K090731, NovaBone Porous) as a control. The results demonstrate that bone remodeling process for BIOACTIVE Strip is equivalent to that of NovaBone Porous. Therefore, no new issues of safety or effectiveness are raised by the *in vivo* performance of BIOACTIVE Strip.

The collagen is sourced from animals born, raised and processed in a GBR1 country free from transmissible spongiform encephalopathies (TSE), including bovine spongiform encephalopathy (BSE) in cattle, scrapie in sheep and chronic wasting disease (CWD) in deer.

Like the predicate devices, BIOACTIVE Strip is supplied as a single-use sterile implantable graft, with double-barrier packaging. The device is sterilized to a sterility assurance level (SAL) of 10^{-6} using ethylene oxide and EO residuals are within acceptable limits.

The processing and packaging methods employed to ensure biological safety of the finished device demonstrate that no new safety issues are raised for BIOACTIVE Strip as compared to the predicate devices.

Conclusion

NovaBone BIOACTIVE Strip is similar to the predicate devices with respect to technical characteristics, performance, and intended use as an orthopedic bone void filler. The information provided for this premarket notification supports substantial equivalence to the primary predicate device, NovaBone Porous (K090731/K060432), with reference to Vitoss (K083033), for the bovine collagen constituent.

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BIOACTIVE Strip

In vivo performance testing (rabbit femoral defect model) and biocompatibility testing were conducted in accordance with the "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device," June 2, 2003. Passing biocompatibility testing demonstrates BIOACTIVE Strip devices are safe for implantation. In the rabbit femoral study BIOACTIVE Strip performed in an equivalent manner to NovaBone Porous, the primary predicate.

Therefore, NovaBone BIOACTIVE Strip bone void fillers are substantially equivalent to the NovaBone Porous predicate device (K090731/K060432).